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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,873	06/27/2003	Hansel M. Fletcher	12423-3	7854
23676	7590	06/09/2004	EXAMINER	
SHELDON & MAK, INC 225 SOUTH LAKE AVENUE 9TH FLOOR PASADENA, CA 91101			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,873

Applicant(s)

FLETCHER, HANSEL M.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 1 and 2 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-10 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2204.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election

1) Acknowledgment is made of Applicant's election filed 03/24/04 in response to the restriction requirement mailed 02/27/04. Applicant has elected invention II, claims 3-10. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Status of Claims

2) Claims 1-10 are pending.

Claims 1 and 2 are withdrawn from consideration as being directed to non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Elected claims 3-10 are under examination. A First Action on the Merits on these claims is issued.

Information Disclosure Statement

3) Acknowledgment is made of Applicant's information disclosure statement filed 02/02/04. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Priority

4) The instant application is a continuation of application SN 09/762,618, filed 02/09/2001, now US patent 6,585,977, which is a national stage 371 filing of the PCT application PCT/US99/18197, filed 08/11/1999, which is a continuation of application SN 09/133,089, filed 08/12/1998, now US patent 6,254,863. The present application is continuation of application SN 09/803,766, filed 03/12/01, now US patent 6,586,227.

Title

5) The title of the invention is not descriptive. A new title reflective of the subject matter of the claims, --A method of decreasing the growth rate of wild-type *Porphyromonas gingivalis*--, is suggested.

Specification - Informalities

6) The instant specification is objected to for the following reason(s):

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The use of trademarks in the instant specification have been noted in this application, for example, "Quiagen" and "Biospec". Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Each letter of the trademark must be capitalized. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to the trademarks, wherever such recitations appear.

Double Patenting

7) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

8) Claims 3-6 and 7-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and claims 5-8 of the U.S. Patent 6,254,863 ('863). Although the conflicting claims are not identical, they are not patentably distinct from each other, because the methods of the cited claims of the patent '863 are encompassed within the scope of instantly claimed methods that involve the step of administering a *recA* defective mutant of *Porphyromonas gingivalis*.

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It is noted that claims drawn to a method of decreasing the growth or reproduction rate of *Porphyromonas gingivalis* was elected for prosecution in the prior application 09/133,089, issued as US patent 6,254,863. These claims were amended during the prosecution wherein the limitation “decreasing the growth rate or reproduction rate of” was replaced with “decreasing the morbidity and mortality rate associated with infection by”. Additional claims were added in the prior application to a method of decreasing the virulence associated with infection by wild type *Porphyromonas gingivalis* comprising administering a dose of the ATCC 202109 mutant strain of *Porphyromonas gingivalis*. There was no restriction in the prior application between methods of decreasing the growth rate or reproduction rate of *Porphyromonas gingivalis* and methods of decreasing the morbidity and mortality rate associated with infection by *Porphyromonas gingivalis*.

9) Claims 3-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of the U.S. Patent 6,585,977 ('977). Although the conflicting claims are not identical, they are not patentably distinct from each other, because the methods of the cited claims of the patent '977 are encompassed within the scope of instantly claimed methods that involve the step of administering a *recA* defective mutant of *Porphyromonas gingivalis*.

Rejection(s) under 35 U.S.C § 112, First Paragraph

10) Claims 3-10 are rejected under 35 U.S.C § 112, first paragraph, as failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological material is (1) known and readily available to the public; (2) reproducible from the written description, e.g., sequenced; or (3) deposited.

Instant claims are directed to a method of decreasing the growth rate or reproduction rate of *Porphyromonas gingivalis* in a mammal by administering to the mammal a *recA* mutant of *Porphyromonas gingivalis*, which is deposited at the ATCC under accession number 202109 (see pages 2 and 3 of the specification). It is apparent that the recited mutant bacterium, *Porphyromonas gingivalis*, is required to practice the claimed invention. As a required element, it must be known and readily available to the public, or obtainable by a reproducible method set

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forth in the specification, or otherwise be readily available to the public. If not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the recited strain.

At page 4 of the instant specification, it is stated that the recited mutant *Porphyromonas gingivalis* FLL32 has been deposited at the ATCC, Manassas, Virginia and has been given the accession number 202109. An affidavit or declaration by Applicants or assignees, or a statement by an attorney of record who has a registration number and has authority and control over the conditions of deposit over his or her signature, is required. The statement should state that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that **all** restrictions upon public access to the deposit will be **irrevocably** removed upon the grant of a patent on this application and that the deposit will be replaced, if viable samples cannot be dispensed by the depository. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each state. The statement should identify the deposited mutant by its depository accession number, establish that the deposited product is the same as the one described in the specification/claims, and establish that the deposited products were in Applicant's possession at the time of filing. As a means of satisfying the necessary criteria of the deposit rules and to show that the claimed mutant is the same as the one deposited, Applicant may submit a copy of the contract or a notice of acceptance of the mutant by the depository.

Applicants' attention is directed to *In re Lundack*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 C.F.R § 1.801-1.809 for further information concerning deposit practice.

11) Claims 3-10 are rejected under 35 U.S.C § 112, first paragraph, because the specification while being enabling for a method of administering to a mammal a dose of the non-virulent *recA* defective mutant strain of *Porphyromonas gingivalis*, FLL32, which is deposited at the ATCC under the accession number 202109, does not reasonably provide enablement for such a method wherein any non-virulent *recA* defective mutant of *Porphyromonas gingivalis* other than the deposited strain is administered to a mammal, and for a method wherein FLL32 or any other *recA*

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mutant decreases the growth or reproduction rate of wild-type or mutant *Porphyromonas gingivalis* in any mammal, as claimed in a broad sense.

Instant claims are evaluated based on *Wands* analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- The quantity of experimentation necessary (time and expense);
- The amount of direction or guidance presented;
- The presence or absence of working examples of the invention;
- The nature of the invention;
- The state of the art;
- The relative skill of those in the art;
- The predictability or unpredictability of the art; and
- The breadth of the claims.

Example III of the instant specification provides description for the claimed method that uses the FLL32 mutant strain of *Porphyromonas gingivalis*. However, this description is not commensurate in scope with the evidence within the specification. The instant application claims a method of decreasing growth and reproduction rate in a mammal, including a human, by administering any avirulent, *recA* defective mutant of *Porphyromonas gingivalis*, yet does not provide any evidence showing that administration, to any mammal let alone a human, of such a mutant, including the FLL32 mutant, results in decreased growth and reproduction rates of a non-virulent or wild type *Porphyromonas gingivalis*, before or after administration of the *recA* defective mutant *Porphyromonas gingivalis*. The growth or reproduction rate of a virulent or non-virulent, a mutant or non-mutant *Porphyromonas gingivalis* has not been measured or quantified either before or after the administration of the *recA* mutant of *Porphyromonas gingivalis* to a mammal, including a human. This is critical since whether or not a non-virulent mutant of a bacterial strain decreases the growth or reproduction rate of a bacterium on administration to a mammal is an unpredictable event, since such an effect is also dependent on the host factors and the virulence or non-virulence and/or the degree of virulence of the challenging or infecting strain of *Porphyromonas gingivalis*. Furthermore, the full scope of the claims is not enabled, because both the instant specification and the art recognize unpredictability

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in obtaining *recA* defective mutants of *Porphyromonas gingivalis* that are non-virulent. For instance, the instant specification describes the FLL32 strain of *Porphyromonas gingivalis* to be a *recA* defective mutant that lacked hemolytic activity on blood agar, lacked the proteolytic activity and lacked black pigmentation (see page 4, last full paragraph) and which exhibited substantially reduced virulence when introduced into mammals (see paragraph bridging pages 4 and 5). However, three other *recA* defective mutant strains of *Porphyromonas gingivalis*, FLL33, FLL34 and FLL35, displayed beta hemolytic activity and black pigmentation similar to the wild-type W83 (see page 9). For example, the FLL33 mutant showed more proteolytic activity than the wild-type W83 (see pages 9 and 10). The specification explicitly states that “the inactivation of the *recA* gene in *Porphyromonas gingivalis* FLL33 did not significantly affect the virulence of *Porphyromonas gingivalis*”, but the “mutation in the FLL32 strain significantly affected the virulence of *Porphyromonas gingivalis*” (see page 15, last full paragraph). The art also taught that the wild-type W83 strain and the *recA* mutant FLL33 showed the same level of virulence. See Fletcher HM. In: *Abstracts in Microbial Pathogenesis*, page 101, abstract B-424, Miami Beach, Florida, May 4-8, 1997 (Applicant’s IDS) and Fletcher *et al. Infect. Immun.* 65: 4592-4597, 1997 (Applicant’s IDS). It is unlikely that such a *recA* defective mutant which still maintains its virulent properties would decrease the growth or reproduction rate of a wild-type or non-wild-type *Porphyromonas gingivalis*, absent evidence to the contrary. Due to this demonstrated unpredictability in producing a *recA* mutant that is functional as recited, i.e., non-virulent, the enablement of a representative number of non-virulent *recA* mutants of *Porphyromonas gingivalis* is critical for one of ordinary skill in the art to reproducibly practice the full scope of the methods as claimed. The entire scope of the instant claims is viewed as being non-enabled for reasons set forth above. Undue experimentation would have been required by one of skill in the art at the time of the effective filing date of the instant application to reproducibly practice the invention as claimed due to the lack of enabling disclosure, the lack of specific guidance, the lack of working examples enabling the entire scope, the demonstrated unpredictability as described within the specification and as reflected in the state of the art, the quantity of experimentation necessary, and the breadth of claims.

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Rejection(s) under 35 U.S.C § 112, Second Paragraph

12) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

13) Claims 3-10 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant(s) regards as the invention.

(a) Claim 3 depends improperly from a non-elected claim.

(b) Claim 7 is indefinite and confusing in the recitation: “decreasing the growth rate or reproduction rate of *Porphyromonas gingivalis*” by administering a “non-virulent, *recA* defective mutant of *Porphyromonas gingivalis*”, because it is unclear whether the growth rate being decreased is of the mutant *Porphyromonas gingivalis*, or wild-type or virulent *Porphyromonas gingivalis*. Clarification/correction is requested.

(c) Claim 6 is confusing and/or grammatically incorrect in the recitation: ‘administered is between about 1×10^3 and 1×10^7 the mutant’.

(d) Claim 8 is incomplete or confusing in having what appear to be two periods. The second line of the claim does not make sense.

(e) Claim 10 is vague, indefinite and/or confusing in the recitation: ‘injecting mutant of *Porphyromonas gingivalis*, wherein the dose is between bacteria’, because it is unclear what ‘bacteria’ Applicant is referring to. The term ‘bacteria’ is of much broader scope than the narrower term ‘mutant of *Porphyromonas gingivalis*’. It is unclear whether Applicant intends the recited dose to contain --said mutant-- as opposed to ‘bacteria’.

(f) Claims 5 and 6 and claims 8-10, which depend directly or indirectly from claim 3 or 7, are also rejected as being indefinite, because of the vagueness or indefiniteness identified above in the base claim

Remarks

14) Claims 3-10 stand rejected.

15) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile

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transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

16) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER